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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,325	01/25/2005	Stanley George Bonney	PG4886-C USW	9222

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EXAMINER	
COLLINS, MICHAEL	
ART UNIT	**PAPER NUMBER**
3651	

MAIL DATE	DELIVERY MODE
06/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,325	BONNEY ET AL.	
	Examiner	Art Unit	
	Michael K. Collins	3651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/10/06, 1/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "442". Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. MPEP, section 2173.05(p) states, "A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph." Id. Claim 24 recites the machine including the medicament dispenser device and the method comprising administering an effective amount of medicament. Since claim 24 claims both an apparatus and the method steps of using the apparatus, this claim is indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-22, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Crowder et al. (USP 6,889,690).

Regarding Claim 1, Crowder et al. disclose a medicament dispenser device (10) for use in the delivery of a combination medicament product, the device comprising:

- a first medicament container (100s) for containing a first medicament component;
- first release means (200a) for releasing the contents of said first medicament container;
- at least one further medicament container (100s) for containing at least one further medicament component;
- at least one further release means (200b) for releasing the contents of each said at least one further medicament container; and
- mixing means for promoting the mixing of the released contents of the first and at least one further medicament container, wherein the first medicament component is kept separate from the at least one further medicament component until the point of release thereof for delivery in combination (see column 18 lines 1-27).

Regarding Claim 2, Crowder et al. disclose a medicament dispenser device according to claim 1, wherein said mixing means promotes mixing of said released contents immediately prior to delivery in combination thereof (see column 18 lines 1-27).

Regarding Claim 3, Crowder et al. disclose a medicament dispenser device according to claim 1, wherein the mixing means promotes mixing of the released contents as an integral part of the release and delivery in combination thereof (see column 18 lines 1-27).

Regarding Claim 4, Crowder et al. disclose a medicament dispenser device according to claim 1, wherein the mixing means promotes of the released contents by making use of the energy inherent in the release and delivery in combination thereof (see column 18 lines 1-27).

Regarding Claim 5, Crowder et al. disclose a medicament dispenser device according to claim 1, wherein the mixing means promotes mixing of the released contents by making use of energy input by the patient (see column 18 lines 1-27).

Regarding Claim 6, Crowder et al. disclose a medicament dispenser device according to claim 1, wherein the mixing means provides for turbulent mixing of the released contents (see column 18 lines 1-27).

Regarding Claim 7, Crowder et al. disclose a medicament dispenser device according to claim 1, wherein the mixing means comprises one or more mechanical mixing promoters comprising mechanical features arranged to promote mixing (see column 18 lines 1-27).

Regarding Claim 8, Crowder et al. disclose a medicament dispenser device according to claim 7, wherein said one or more mechanical mixing promoters comprise mechanical features selected from the group consisting of baffles, propellers, paddles, vanes and venture (see Figures 15A-15C).

Regarding Claim 9, Crowder et al. disclose a medicament dispenser device according to claim 1, wherein the mixing means comprises a mixing chamber including an inlet for receiving released medicament contents from each medicament container and a common outlet for delivery of combination medicament product to the patient for delivery (see column 19 lines 1-51).

Regarding Claim 10, Crowder et al. disclose a medicament dispenser according to claim 9, wherein the inner surface of the mixing chamber is shaped to promote mixing (see column 19 lines 1-51).

Regarding Claim 11, Crowder et al. disclose a medicament dispenser according to claim 10, wherein the inner surface of the mixing chamber is provided with one or more indentations or protrusions (see column 19 lines 1-51).

Regarding Claim 12, Crowder et al. disclose a medicament dispenser device according to claim 1, wherein the mixing means is provided with exercitation means for energising the mixing of the released contents.

Regarding Claim 13, Crowder et al. disclose a medicament dispenser device according to claim 9, in the form of an inhalation device wherein, the mixing chamber is arranged to harness the energy provided by a patient's inward breath to promote mixing of the released contents (see column 20).

Regarding Claim 14, Crowder et al. disclose a medicament dispenser device according to claim 13, wherein the mixing chamber provides for venturi channeling of said patient's inward breath (see Figures 15A-15B).

Regarding Claim 15, Crowder et al. disclose a medicament dispenser device

according to claims claim 1, wherein the device comprises the first medicament container and only one further medicament container.

Regarding Claim 16, Crowder et al. disclose a medicament dispenser device according to claim 1, wherein the device includes at least one actuation indicator (20g) associated with the first medicament container the at least one further medicament container.

Regarding Claim 17, Crowder et al. disclose a medicament dispenser device according claim 1, wherein the device includes a timing control for controlling the relative time of release of contents from the first and at least one further medicament container (see Figure 22).

Regarding Claim 18, Crowder et al. disclose a medicament dispenser device according to claim 17, wherein the first medicament container contains said first medicament and the at least one further medicament container contains said at least one further medicament (see column 8 lines 1-28).

Regarding Claim 19, Crowder et al. disclose a medicament dispenser device according to claim 18, wherein the first medicament comprises a bronchodilator and the at least one further medicament comprises an anti-inflammatory (see column 8 lines 1-28).

Regarding Claim 20, Crowder et al. disclose a medicament dispenser device according to claim 19, wherein said bronchodilator is a beta-agonist and said anti-inflammatory is a steroid (see column 8 lines 1-28).

Regarding Claim 21, Crowder et al. disclose a medicament dispenser device

according to claim 20, wherein said bronehodilator is selected from the group consisting of salbutamol, salmeterol, formoterol and any salts or solvates thereof and mixtures thereof (see column 8 lines 1-28).

Regarding Claim 22, Crowder et al. disclose a medicament dispenser device according to claim 20, wherein said anti-inflammatory is selected from the group consisting of a beclomethasone ester, fluticasone ester, budesonide and any salt or solvates thereof and mixtures thereof (see column 8 lines 1-28).

Regarding Claim 24, Crowder et al. disclose a method of treating a respiratory disorder in a patient in need thereof comprising administering an effective amount of medicament suitable for treating said respiratory disorder to the patient by inhalation from a medicament dispenser according to claim 1.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael K. Collins whose telephone number is (571) 272-8970. The examiner can normally be reached on 8:30 am - 5:00 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene O. Crawford can be reached on (571) 272-6911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M.C.
5/31/2007

GENE O. CRAWFORD
SUPERVISORY PATENT EXAMINER